

Amendment and Response
Applicants: Patrick P. Russo et al.
Serial No.: 10/074,740

Attorney Docket: EV31014US

REMARKS

Claims 2 to 6, 8 to 11, 13, 16, 17, 19, 21, 25, 27, and 31 to 38 are pending in this application. Claims 2 to 6, 8 to 11, 13, 16, 17, 19, 21, 25, 27, 33, and 35 to 38 are currently amended. All of these claims find support in the original application as filed and in the U.S. provisional application 60/268,773 as filed, priority of which is claimed under 35 U.S.C. § 119.

Applicants thank Examiner Tan-Uyen T. Ho for the courtesy of a series of e-mail communications between February 10, 2005 and March 4, 2005. These electronic communications discussed amendments to the claims to distinguish over the rejections of record in the Final Office Action of October 26, 2004. In electronic communications on February 28, 2005 and March 4, 2005, Examiner Ho stated that she would issue an Office Action to make a rejection on a newly found reference. That Office Action issued on April 12, 2005.

The present Amendment and Response includes amendments to the claims in accordance with the noted series of e-mail communications. Applicants understand that the claims as presently amended patentably distinguish over the rejections of record in the Final Office Action of October 26, 2004. In addition, Applicants respectfully submit that (1) the newly applied reference, WO 01/12082 A1, related U.S. Patent Pub. 2002/0058963 A1, and any patent that may issue from the application corresponding to U.S. Patent Pub. 2002/0058963 A1 are not available to reject the presently amended claims, and (2) the presently amended claims patentably distinguish over WO 01/12082 A1, U.S. Patent Pub. 2002/0058963 A1, and any patent that may issue from the application corresponding to U.S. Patent Pub. 2002/0058963 A1.

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Drawings

The Examiner is requested to indicate on the record that the drawings are accepted or to indicate specifically any objections thereto.

Information Disclosure Statements

Applicants note that, in the Office Action of May 14, 2004, the Examiner returned initialed and dated sheets 2 of 3 and 3 of 3 of the PTO-1449 forms for the Information Disclosure Statement submitted on July 5, 2002. However, the Examiner did not include initialed and dated sheet 1 of 3 of the PTO-1449 forms for the Information Disclosure Statement submitted on July 5, 2002. Applicants respectfully request that the Examiner initial and return sheet 1 of 3 from the July 5, 2002 Information Disclosure Statement. For the Examiner's convenience, a copy of sheet 1 of 3 is enclosed.

Rejection Over U.S. Patent No. 6,663,651 B1 to Krolik et al.

The Examiner rejected claims 2 to 11, 13, 15 to 21, 25, 27, and 31 to 38 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,663,651 B1 (Krolik et al.).

Applicants respectfully traverse this rejection of the claims. The rejection of claims 7 and 15 is moot with the cancellation of these claims. With the present amendments to the claims, as agreed between Examiner Ho and Applicants' representative in the above-referenced series of e-mail communications, Krolik does not anticipate any of the claims.

Amended independent claims 8, 17, 27, and 35 now each require:

[T]he wall having an undeflected configuration prior to retrieval of the embolic protection device into the lumen and a deflected configuration during retrieval of the embolic protection device into the lumen ... a distance between proximal and distal ends of the wall

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is less in the deflected configuration than in the undeflected configuration.

Krolik et al. does not disclose or suggest that the distance between the proximal and distal ends of the distal tip wall is less in the deflected configuration, during embolic protection device retrieval, than in the undeflected configuration, before embolic protection device retrieval. Claims 8 and 35 require that the distal end of the wall of the distal tip is rolled inwardly in the deflected configuration. Krolik et al. does not disclose or suggest this feature of the claims.

The Examiner contended that Krolik et al. discloses catheters having flexible tips including walls capable of forming into a deflected configuration during retrieval of the embolic protection device into the lumen and that the contact with the embolic protection device could cause the distal tip of Krolik et al. to curve inwards. Applicants disagree. Krolik et al. does not explicitly disclose a deflected configuration in which the distal tip curves inwardly. The Examiner's position was that the device of Krolik et al. could be used so that it deflects the distal tip and causes the distal tip to curve inwardly. Applicants' position is that Krolik et al. does not teach or suggest a deflected configuration in which the distance between proximal and distal ends of the wall is less in the deflected configuration than in the undeflected configuration.

In the October 26, 2004 Final Office Action, the Examiner contended that if filter 30 contained a large amount of embolic material, the distal tip would deflect and curve inward before the expansion slits 52 permit the sheath 50 to expand and accept the filter. This interpretation is contrary to the specification and figures. Krolik et al. states at column 5, lines 11 to 15, that "[e]xpansion slits 52 permit the curved portions of distal end 51 to expand to accept a vascular filter when adapter 50 is advanced along guidewire 59, so that opening 53 at least partially accommodates a portion of a deployed vascular filter." See, Figure 5B, which

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shows the filter 30 being received within adapter 50. As described in the specification in column 5, and shown in Fig. 5B, the distance between proximal and distal ends of the wall is the same in the deflected configuration and in the undeflected configuration. This contrasts with the claimed invention in which the distance between proximal and distal ends of the wall is less in the deflected configuration than in the undeflected configuration.

Further, Krolik et al. does not teach or suggest that the distal end of the wall of the distal tip is rolled inwardly in the deflected configuration, as required by claims 8 and 25. Accordingly, Applicants respectfully request that the Examiner withdraw this rejection of the claims.

Rejection Over International Publication No. WO 01/12082 A1 to Vale et al.

The Examiner rejected claims 2 to 11, 13, 15 to 21, 25, 27, and 31 to 38 under 35 U.S.C. § 102(a) as being anticipated by International Publication No. WO 01/12082 A1 to Vale et al. ("Vale international publication").

Applicants respectfully traverse this rejection of the claims. The rejection of claims 7 and 15 is moot with the cancellation of these claims. This response also considers the potential applicability of any rejections based on U.S. Patent Publ. 2002/0058963 A1 to Vale et al. ("Vale U.S. publication") and any rejections based on any U.S. patent that may issue from the application corresponding to the Vale U.S. publication ("potential Vale U.S. patent") under 35 U.S.C. §§ 102(a) and (e). The Vale publications and any potential Vale U.S. patent are not valid references against this application and do not anticipate or render obvious any of the claims.

The Vale publications and any potential Vale U.S. patent are not valid references against this application. Section 102(a) provides that "A person shall be entitled to a patent unless (a) the invention was known or used by others in this

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country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent." The earliest effective date of the Vale international publication is February 22, 2001, its publication date. The earliest effective date of the Vale U.S. publication is May 16, 2002, its publication date. Any potential Vale U.S. patent will have an effective reference date under 35 U.S.C. § 102(a) of its issue date. The present application claims the benefit of U.S. provisional patent application 60/268,773, filed February 14, 2001, and the pending claims are entitled to this February 14, 2001 filing date. Because the filing date of the provisional application is before the effective date of the Vale publications and any potential Vale U.S. patent, none of these references are available to reject any of the present claims under 35 U.S.C. § 102(a).

Because the Vale publications have an international filing date before November 29, 2000, the effective date for the amendments to 35 U.S.C. § 102(e), any effective prior art dates of the Vale publications are determined according to 35 U.S.C. § 102(e) in effect before November 29, 2000:

A person shall be entitled to a patent unless ...

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

According to 35 U.S.C. § 102(e) in effect before November 29, 2000, the Vale international publication is not a reference against this application because no patent has issued. The Vale international application corresponding to the Vale international publication will never become a reference under 35 U.S.C. § 102(e) because the requirements of paragraphs (1), (2), and (4) of section 371(c) were never fulfilled. Instead, the Vale applicants filed a continuation of the

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international application on January 14, 2002. This continuation application was published as U.S. Patent Publ. 2002/0058963 A1 ("Vale U.S. publication"). Accordingly, the effective date of the Vale U.S. publication is January 14, 2002. Because the filing date of the provisional application is before the effective date of the Vale U.S. publication, this reference is not available to reject any of the present claims under 35 U.S.C. § 102(e).

The presently amended claims patentably distinguish over the disclosures of the Vale publications and any potential Vale U.S. patent. FIGS. 23 to 26 and page 17, lines 13 to 31, of the Vale international publication describe a retrieval device 70 with a tapered distal extension 72 of the main body of a retrieval catheter 73. The tapered distal extension 72 has an open mouth 75 through which a filter 71 is retrieved. FIGS. 23 to 26 show that the tapered distal extension 72 tapers and does not have a rolled or curved tip configuration. By contrast, the distal end 24 of the distal tip 10 of the present rolled tip recovery catheter ends in a rolled or curved tip configuration (page 9, line 21, to page 10, line 8, of the specification):

The distal end 24 of the distal tip 10 can have a rolled tip as at 32. The portion of the wall 34 at the distal end 24 of the distal tip 10 can be rolled inward toward the axis 52 of the lumen 30 to form the rolled tip 32.

The wall 34 of distal tip 10 has an inside surface 36 and an outer surface 38. At the rolled tip 32, end 22 is shown as facing inwardly toward the lumen 30. The end 22 is facing generally radially inwardly. The outer surface 38, over most of the length of the distal tip 10, faces generally radially outwardly. However, at the rolled tip 32, the outer surface 38 is curved so as to face in the distal direction to define a distal contact surface 26.

The present specification describes advantages for the present curved or rolled tip recovery catheter over the type of retrieval catheter of the Vale

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publications and any potential Vale U.S. patent (present specification, page 10, line 10, to page 12, line 23):

The rolled tip 32 is especially designed for crossing a stented or otherwise constricted region of a blood vessel 54. A stent is a generally tubular member having a wire wall defining the boundary of the blood vessel lumen. The catheter must pass through the lumen defined within the stent in order to cross the stented region. As a catheter in accordance with the prior art is advanced within the blood vessel, the distal end of the catheter can become caught against an axial end of the stent. This is particularly true at a curve in the blood vessel 54, or when the stent is underexpanded or incompletely deployed. More specifically, the end of the catheter may engage an axial end of the stent. This can prevent the catheter from being able to advance farther into the blood vessel 54. Similar problems may occur in a constricted or stenosed region of a blood vessel.

The rolled tip configuration in accordance with the present invention can prevent such problems. A catheter utilizing the distal tip 10, having a rolled tip 32 described herein, is inserted into a blood vessel. The distal tip 10 is advanced to a stented region of the blood vessel. The rolled tip 10 is curved, as previously discussed, such that the outer portion of the wall 34 at the rolled tip 32 defines contact surface 26. As the distal tip 10 is advanced through the region, the contact surface 26 of the rolled tip 32 may engage a stent. The rolled tip 32 prevents the distal tip 10 from becoming impassibly engaged with the stent. As the distal tip 10 is urged across the stented region, the rolled tip 32 may contact the stent, but it will deflect from the point of contact and be urged away from the stent. Thus, where the outer surface 38 contacts the stent, the distal tip 10 can continue advancing past the stent as a result of non-engagement with the axial end of the stent and allowing the distal tip 10 to continue advancing within the blood vessel 54.

The distal tip 10 can also function to capture, for example, a protection device 58 within the lumen 30. Lumen 30 is of a given diameter. The distal tip 10 is connected to a catheter such that the

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distal tip lumen 30 is in smooth communication with a catheter lumen 42.

A device 58 to be captured within the lumen 30 might be, for example, an embolic protection device. A guidewire extends proximal with respect to the protection device 58, extending through the lumen 30 of the distal tip 10 and catheter 40. The device is typically positioned distal to the distal tip 10 and is secured to the guidewire. The protection device 58 has a diameter that is typically greater than that of the distal tip distal end 24.

Again, the distal tip 10 is made of a compliant material such that the protection device 58 can be facilely received into the distal tip lumen 30. As the protection device 58 is drawn toward the distal tip 10, it will first contact the rolled tip 32 at the contact surface 26. The rolled tip 32 may be urged elastically inward as the device enters the lumen 30 (FIG. 3). After the device 58 has been fully drawn in the proximal direction relative to distal tip 10, the rolled tip 32 reaches a point where it ceases to be engaged by the device, and it will return to its undeflected configuration (FIG. 5). As the device 58 is being drawn into the lumen 30, however, the lumen 30 will adapt to conformingly hold the device 58 therein and rolled tip 32 will expand radially to accommodate the periphery of the device (FIG. 4). The device 58 will eventually have become fully housed within the catheter lumen, and the distal tip 10 returns, as discussed above, substantially to its original configuration.

The presently amended independent claims all require this curved distal tip configuration. Claim 8 requires:

a wall defining a distal tip, said tip defining a lumen, the wall having a proximal end and a distal end, wherein said wall has a curved portion at said distal end curving inwardly toward an axis of said lumen ...

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Claim 17 requires:

a catheter having a distal tip comprising a wall defining a lumen wherein said wall has a wall thickness which tapers from a greater thickness at a proximal end of the wall to a lesser thickness at a distal end of the wall and wherein at said distal end said wall curves inwardly towards said lumen ...

Claim 27 requires:

a catheter having a tubular member connected to and in communication with a catheter distal end; wherein said tubular member has a wall forming a lumen wherein said wall has a thickness that tapers in a decreasing manner from a wall proximal end towards a wall distal end, said distal end of said wall curving inwardly towards said lumen ...

Claim 35 requires:

a distal tip having a wall with an inner surface and an outer surface, the wall having a distal end and a proximal end, the inner surface defining a lumen, the outer surface tapering inwardly toward the distal end, the wall having a thickness between the inner surface and outer surface which tapers in a decreasing manner in a direction from the proximal end to the distal end, the distal end of the wall curving inwardly toward the lumen ...

The Vale publications and any potential Vale U.S. patent do not form the basis for any valid rejection of the presently amended claims under any provision of 35 U.S.C. § 102. Accordingly, Applicants respectfully request that the Examiner withdraw this rejection of the claims.

In view of the above amendments and remarks, Applicants respectfully request that the Examiner withdraw the rejections of the claims.

If any additional fees are due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 16-2312. If a fee is required for

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an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account.

Respectfully submitted,

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By



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